INTRODUCTION

ORA LABORATORY MANUAL

FDA Office of Regulatory Affairs
Division of Field Science

DOCUMENT NO.: LM-TOC

VERSION NO.: 1.1

FINAL

EFFECTIVE DATE:

10-01-03

TABLE OF CONTENTS

Introduction

ACRA Foreword
Division of Field Science Introduction
Table of Contents
Appendix A – ISO 17025/ORA U/Laboratory Manual cross reference
Appendix B – Acknowledgements

Volume I ORA Laboratory Manual of Quality Policies

Volume II ISO 17025 ORA Laboratory Procedures

Section 1 – Management Requirements (Templates)

| ORA-LAB.4.1 | Organization (refer to Vol. I section 4.1; Org. charts) |
|--------------|---|
| ORA-LAB.4.2 | Quality System (refer to Vol. I section 4.2) |
| ORA-LAB.4.3 | Document Control and Management |
| ORA-LAB.4.4 | Request, Tenders, Contracts (refer to Vol. I section 4.4) |
| ORA-LAB.4.5 | Subcontracting (not applicable to field labs) |
| ORA-LAB.4.6 | Purchasing and Receipt |
| ORA-LAB.4.7 | Client Services (refer to Vol. I section 4.7) |
| ORA-LAB.4.8 | Complaints |
| ORA-LAB.4.9 | Control of Non-conforming Work |
| ORA-LAB.4.10 | Corrective Action Procedure |
| ORA-LAB.4.11 | Preventive Action Procedure |
| ORA-LAB.4.12 | Record and Data Management |
| ORA-LAB.4.13 | Audits |
| ORA-LAB.4.14 | Management Review |

Section 2 – Technical Requirements

| ORA-LAB.5.1 | General N/A |
|--------------|---|
| ORA-LAB.5.2 | Personnel :Training Procedure |
| ORA-LAB.5.3 | Facilities and Environmental Conditions (linked to Vol. III, sec. 2 |
| ORA-LAB.5.4 | Test Methods & Validation |
| | 5.4.5 Methods, Method Verification and Validation |
| | 5.4.6 Estimation of Uncertainty of Measurement |
| ORA-LAB.5.5 | Equipment |
| | 5.5.1 Instrument and Equipment Documentation and Records |
| ORA-LAB.5.6 | Measurement Traceability |
| ORA-LAB.5.7 | Sampling (not applicable to field labs) |
| ORA-LAB.5.8 | Sample Management |
| ORA-LAB.5.9 | Assuring the Quality of Test Results |
| ORA-LAB.5.10 | Reporting Laboratory Data |
| | |

This document is uncontrolled when printed: 10/21/2004 For the most current and official copy, check the Intranet at htt://web.ora.fda.gov/dfs/policies/manuals/default.htm

Volume III Laboratory Operations, Applications and Programs

- Section 1 Environmental Health and Safety
- Section 2 Chain of Custody Sample Handling
- Section 3 Recording of Results Analyst's Worksheet
- Section 4 Basic Statistics and Presentation
- Section 5 Analysts on Inspection
- Section 6 Research
- Section 7 Private Laboratory Guidance
- Section 8 Courtroom Testimony

Volume IV Laboratory Training (linked to ORA U)

- Section 1 Laboratory Orientation
 - Answer Key: Laboratory Orientation
- Section 2 Microbiology
 - Answer Key: Microbiology
- Section 3 Drug Analysis
 - Answer Key: Drug Analysis
- Section 4 Microanalytical and Filth Analysis
- Section 5 Pesticides Analysis
 - Answer Key: Pesticides Analysis
- Section 6 Elemental Analysis
 - Answer Key: Elemental Analysis
- Section 7 Mycotoxin Analysis
 - Answer Key: Mycotoxin Analysis
- Section 8 Sensory Analysis
 - Answer Key: Sensory Analyis
- Section 9 Seafood Chemistry
 - Answer Key: Seafood Chemistry
- Section 10 Food Standards & Additives
 - Answer Key: Food Standards and Additives
- Section 11 Nutrient Analysis
 - Answer Key: Nutrient Analysis
- Section 12 Radioactivity
 - Answer Key: Radioactivity
- Section 13 Engineering
- Section 14 Consumer Complaints/Product Tampering